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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,328	11/18/2003	Richard A. Terwilliger	WORLD-01004US2	5231
23910	7590	03/24/2005	EXAMINER	
FLIESLER MEYER, LLP FOUR EMBARCADERO CENTER SUITE 400 SAN FRANCISCO, CA 94111			VENIAMINOV, NIKITA R	
			ART UNIT	PAPER NUMBER
			3736	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/716,328	<b>Applicant(s)</b> TERWILLIGER ET AL. 	
	<b>Examiner</b> Nikita R Veniaminov	<b>Art Unit</b> 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 5-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>02/16/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. **Claims 1-3 and 8** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 6,514,193) in view of Mentor Corporation (NASD, MNTR) cited by Applicant and Coniglione (US 5,713,828).

Kaplan ('193) teaches a prescription method of treating tissue comprising the steps of:

**(Claims 1 and 8)** accepting a tissue treatment plan for the tissue to be treated, which treatment plan specifies a number of and a spacing of treatment seeds, said treatment seeds to be provided in a strand (see column 14, lines 25-41; column 15, lines 57-67 and column 16, lines 1-20. Examiner states, that a prescription method of treating tissue comprising the step of accepting a tissue treatment plan is inherently exists in the invention of Kaplan ('193). The seed chains are made using different sized spacers to deliver a "predetermined" amount of radiation. It would not be possible to pre-make these seed chains unless a plan has been selected);  
creating a treatment strand by threading treatment seeds onto a material (see Figure 5A and 5B; column 14, lines 25-41 and column 15, lines 1-20); and

fixing the seeds at intervals on the material, wherein at least some of the intervals can be independently set to a desired length (see Figures 5A - 5B and column 14, lines 34-41).

**(Claim 3)** said accepting step included accepting a treatment plan that specifies a plurality of radioactive seeds and an optimal spacing between adjacent seeds and around each of two end seeds (see column 14, lines 25-41; column 15, lines 57-67; column 16, lines 1-20 and Examiner's explanation above); and wherein said creating step includes creating strands to said spacings (see column 14, lines 25-41; column 15, lines 57-67; column 16, lines 1-20).

Kaplan ('193) implicitly teaches the steps of a prescription method of treating tissue, as described above, but he does not explicitly teach a step of accepting tissue treatment plan of the tissue to be treated. However, Mentor Corporation (NASD, MNTR) teaches a step of accepting a tissue treatment plan for the tissue to be treated, which plan specifies a number and spacing of treatment seeds to be provided in a strand. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the method steps of Mentor Corporation (NASD, MNTR) with the treatment plan of Kaplan ('193) to provide greater planning flexibility, improved safety, improved control and better documentation.

Kaplan ('193) does not teach a step of creating a treatment strand by threading a material through a bore through the treatment seeds. Coniglione ('828) teaches a device formed from a hollow-tube-shaped seed-substrate,

allowing the easy association of the device with suture material (abstract, column 11, lines 5-19, column 15, lines 38-46 and Figures 4-5). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the method step of creating of the treatment strand of Coniglione ('828) in the method of Kaplan ('193) to provide axially rigid and radially flexible connection between seeds at predetermined spacing and to improve accuracy of emplacement the strand in the tumor.

**(Claim 2 and elements of claim 8)** wherein said fixing step is performed by crimping the material between adjacent treatment seeds, wherein the crimping prevents displacement of the treatment seeds on the treatment strand (see column 15, lines 1-3).

3. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 6,514,193) in view of Rapach et al. (US 2004/0015037 A1), and further in view of Reit et al. ("ULTRASONICALLY GUIDED TRANSPERINEAL SEED IMPLANTATION OF THE PROSTATE: MODIFICATION OF THE TECHNIQUE AND QUALITATIVE ASSESSMENT OF IMPLANTS") cited by Applicant.

Kaplan ('193) and Rapach et al. ('5037) teach a prescription method of treating tissue as described in paragraph 2 above, but they do not teach a method, wherein an accepting step includes accepting a treatment plan created an imaging device.

However, Reit et al. teach an ultrasonically guided (guided by an imaging device) implantation techniques, which allows for planning of the optimal seed configuration (see page 555, left column, lines 19-24; page 555, right column, lines 5-17 and page 556, right column, lines 41-47).

In the absence of showing any criticality, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the method step of Reit et al. with the method steps of Kaplan ('193) and Rapach et al. ('5037) to accept a plan for an ideal seeds distribution and optimal seeds configuration.

4. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 6,514,193) in view of Mentor Corporation (NASD, MNTR) cited by Applicant.

Kaplan ('193) teaches the steps of a prescription method of treating tissue, as described in paragraph 2 above, but he does not teach a method, wherein an accepting step includes accepting a treatment plan created using a software program to specify intervals between adjacent seeds.

Mentor Corporation (NASD, MNTR) teaches a method of using a standard 3-D treatment planning software to specify intervals between seed positions (see page one, lines 11-27).

In the absence of showing any criticality, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the software of Mentor Corporation (NASD, MNTR) in the treatment plan of Kaplan ('193) to

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provide greater planning flexibility, improved safety, improved control and better documentation.

5. **Claims 7 and 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 6,514,193).

Kaplan ('193) teaches a prescription method of treating tissue, as described in paragraph 2 above, wherein a fixing step including melting or other known steps (column 15, lines 1-3), but he does not teach a fixing step including a heating step, wherein the heating step causes a material to expand and fix the seeds in place.

In the absence of showing any criticality, it would have been obvious to one of ordinary skill in the art at the time of the invention to use well known step of fixing, such as heating in the fixing step of Kaplan ('193) to provide strong fixation of seeds on the material, which will expand during heating.

### ***Response to Arguments***

6. Applicant's arguments with respect to **claims 1-6** have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikita R Veniaminov whose telephone number is (571) 272-4735. The examiner can normally be reached on Monday-Friday 8 A.M.-5 P.M..



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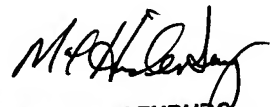
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nikita R Veniaminov  
Examiner  
Art Unit 3736

March 18, 2005.



MAX F. HINDENBURG  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700